UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,827	09/07/2004	Janusz B. Pawliszyn	PAT 804W-2	8910

26123 7590 12/28/2005

BORDEN LADNER GERVAIS LLP
WORLD EXCHANGE PLAZA
100 QUEEN STREET SUITE 1100
OTTAWA, ON K1P 1J9
CANADA

EXAMINER	
DIRAMIO, JACQUELINE A	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/506,827	PAWLISZYN, JANUSZ B.	
	Examiner	Art Unit	
	Jacqueline DiRamio	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *101-109 and 118* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *101-109 and 118* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Currently, claims 1 – 100 and 110 – 117 have been cancelled. Claims 101 – 109 and 118 are pending.

Withdrawn Objections and Rejections

The objections to the specifications have been withdrawn in light of Applicant's amendment to the specification, filed September 14, 2005.

The rejection of claim 110 under 35 U.S.C. 112, second paragraph, has been withdrawn in light of Applicant's cancellation of this claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 101 – 109 and 118 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 101 has been amended to recite the phrase "**an attachment region** disposed on said casing, and **permanently** attachable to said animal or animal tissue during sampling." The terms "**an attachment region**" and "**permanently attachable**" are considered new matter because an attachment region or a permanent attachment of the positioning device is not written or taught in the specification. On page 12, lines 4-15, the positioning device is described, and it is taught that the device can be "rendered attachable to the animal or animal tissue." However, the positioning device, which can encompass a catheter, is subsequently removed from the animal after sampling has finished and therefore, it is not taught that the positioning device is "permanently" attached to the animal or animal tissue. Additionally, a description of an "attachment region" disposed on the casing of the positioning device is not found in the specification, and therefore, it is unclear what encompasses the attachment region (see p14, lines 1-10, as well as Applicant's arguments on p5, lines 8-11, filed October 11, 2005).

In conclusion, the specification does not provide reasonable support to convey to one skilled in the relevant art that the Applicant, at the time the application was filed, had possession of the claimed invention as amended.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 101, 107, 109 and 118 are rejected under 35 U.S.C. 102(b) as being anticipated by Pawliszyn (US 5,691,206).

Pawliszyn teaches a device for solid phase microextraction comprising a fiber, which contains a coating selective for a component of interest (extraction phase), and a hollow needle (positioning device), which contains the fiber and allows for positioning into a sample for microextraction (see column 2, lines 10-21 and Figure 3 in particular). For solid phase microextraction, the extraction process "does not require prior sampling of aqueous material since in-vivo or in-vitro sampling can be conveniently performed," therefore, the device is enabled for positioning of the fiber in animal or animal tissue (see column 5, lines 10-15 in particular).

With respect to claim 107, the hollow needle is further connected to a syringe, which acts as a housing (openable) for the fiber (see column 3, lines 52-56).

With respect to claim 109, the device allows for fiber or fibers to be utilized for the microextraction process (see column 3, lines 53-65 in particular).

With respect to claim 118, the device contains a metal sleeve (needle) 24 in which said fiber is housed, and the metal sleeve is further insertable into the housing (casing), consisting of the syringe (see Figure 2, and column 3, lines 5-56).

Claims 101, 107 and 118 are rejected under 35 U.S.C. 102(b) as being anticipated by Frerot et al. (Solid-Phase Microextraction (SPEM): A new tool in pheromone identification in lipidoptera, *J. High Resol. Chromatogr.* 1997, 20, pp.340-342).

Frerot et al. teach a device for solid-phase microextraction (SPME) utilizing a Supelco™ SPEM holder (positioning device) equipped with a fiber coated with polydimethylsiloxane (extraction phase), wherein the fiber extracts pheromone components from the glands (tissue) of Lepidoptera (animal/insect) (see p340, materials and methods).

With respect to claims 107 and 118, the Supelco™ SPEM holder utilized by Fretot et al. comprises a similar embodiment to the device of Pawliszyn as described above, with a hollow needle (positioning device), which contains the fiber, and a syringe forming the entire housing for the device (see sigmaaldrich.com).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 108 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pawliszyn (US 5,691,206) or Fretot et al. ((Solid-Phase Microextraction (SPEM): A new tool in pheromone identification in lipidoptera, *J. High Resol. Chromatogr.* 1997, 20, pp.340-342) in view of Van Bockel (US 6,743,180).

Both Pawliszyn and Fretot et al., which have been discussed above in the 102 rejection, fail to teach the use of a catheter with the positioning device.

Van Bockel teaches the use of a catheter for introducing a device, i.e. pressure sensor, into an artery. The catheter has an advantage for introducing the device into the body because only a very small operation is required and the catheter allows for the device to be effectively introduced and directed to the proper position (see column 2, lines 20-30 in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device taught by both Pawliszyn and Fretot et al. a catheter as taught by Van Bockel because Van Bockel teaches the benefit of using a catheter to introduce a device into an artery because only a very small operation is required and the catheter allows for the device to be effectively introduced and directed to the proper position..

Claims 102 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pawliszyn (US 5,691,206) or Fretot et al. ((Solid-Phase Microextraction (SPEM): A new tool in pheromone identification in lipidoptera, *J. High Resol. Chromatogr.* 1997, 20, pp.340-342) in view of Basta (US 6,730,096).

Pawliszyn and Fretot et al. further fail to teach the use of a biocompatible protection layer coated on the fibre, wherein the biocompatible layer comprises polypyrrole or derivatised cellulose.

A biocompatible component is one that has compatibility with living tissue or a living system by not being toxic, injurious, or physiologically reactive and not causing immunological rejection (Merriam-Webster's Collegiate Dictionary). Many references teach the use of cellulose derivatives for biocompatible coatings on surgical or implantable devices. Basta teaches a catheter and stabilizing device wherein both the catheter and device are formed of a biocompatible plastic or elastomer, such as a cellulose derivate, i.e. cellulose acetate, which will therefore not cause a toxic or injurious response within the body (see column 5, lines 35-60 in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include on the fiber taught by both Pawliszyn and Fretot et al. a coating comprising a biocompatible protection layer, such as a cellulose derivative, as taught by Basta because it is beneficial to use a biocompatible coating on any device used within the body in order to prevent a toxic or injurious response.

Claim 106 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pawliszyn (US 5,691,206) or Fretot et al. ((Solid-Phase Microextraction (SPEM): A new tool in pheromone identification in lipidoptera, *J. High Resol. Chromatogr.* 1997, 20, pp.340-342) in view of Quay et al. (US 6,287,521).

The devices taught by both Pawliszyn and Fretot et al. contain fibers coated with an extraction phase comprised of polydimethylsiloxane, but fail to teach the use of a fluorescent label or enzyme contained within the extraction phase.

Quay et al. teach the use of a solid phase matrix, such as capillary or coated tubes (hollow fibers), to extract biological markers from mammary fluid (see column 12, lines 8-17 in particular). Reagents, such as immobilized antibodies (bioaffinity agent), are attached to the solid phase matrix in order to bind to the target compound in the sample (see column 12, lines 20-40 in particular). Quay et al. further teach the combination of the solid phase matrix comprising the immobilized antibodies (bioaffinity agent) with a label, such as an enzyme or fluorescent label, which function to display the presence or absence of the target analyte by reacting with the target (see column 12, lines 51-67 in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include on the fiber taught by both Pawliszyn and Fretot et al. an extraction phase comprising immobilized antibodies (bioaffinity agent) and a fluorescent label or enzyme as taught by Quay et al. because Quay et al. teach the benefit of using the immobilized antibodies to bind the target of interest and the benefit of a fluorescent label to display the presence or absence of this target analyte.

Claim 104 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pawliszyn (US 5,691,206) or Fretot et al. ((Solid-Phase Microextraction (SPEM): A new

tool in pheromone identification in lipidoptera, *J. High Resol. Chromatogr.* 1997, 20, pp.340-342) in view of Colburn et al. (US 2003/0183758).

Both Pawliszyn and Fretot et al. meet the structural limitations of both the fiber and extraction phase, therefore, enabling the device to be useful in a variety of analytical instruments, however, Pawliszyn and Fretot et al. fail to teach the use of MALDI-TOFMS analysis specifically.

Colburn et al. teach that matrix-assisted laser desorption/ionization (MALDI) in combination with time-of-flight (TOF) analyzers have become one of the standard approaches to characterization by mass spectrometry of non-volatile, thermally labile substances such as peptides, proteins and polymers (see paragraph 0003, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the MALDI-TOFMS combination as taught by Colburn et al. as the analytical instrument for the device of Pawliszyn and Fretot et al. because Colburn et al. teach the benefit of using MALDI-TOF analyzers because they have become one of the standard approaches to characterization by mass spectrometry of non-volatile, thermally labile substances such as peptides, proteins and polymers.

Claim 105 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pawliszyn (US 5,691,206) or Fretot et al. ((Solid-Phase Microextraction (SPEM): A new tool in pheromone identification in lipidoptera, *J. High Resol. Chromatogr.* 1997, 20, pp.340-342) in view of Riviere et al. (US 2003/0180954).

Pawliszyn and Fretot et al. further fail to teach the addition of a calibrant to the extraction phase of the fiber.

Riviere et al. teach the use of polydimethylsiloxane coated fibers as skin-imitating membranes in order to study permeation of chemicals into these membranes (see paragraph 0037). The absorption parameters, referred to as molecular descriptors, of each chemical compound is obtained by comparing to its calibration standard, wherein the standards were created by analyzing fifty compounds and their subsequent molecular descriptors (see paragraphs 0167-0169). The calibration standards determine the system constants, which reflect the properties of the membrane (fibers) and will not change with different solutes, therefore, the molecular descriptors of unknown/study compounds can be obtained (see paragraph 0170).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include on the extraction phase of the fibers of Pawliszyn and Fretot et al. a calibration standard (calibrant) as taught by Riviere et al. because Riviere et al. teach the benefit of using calibration standards to determine the system constants because they reflect the properties of the fibers, which will not change and thus enable the absorbance of unknown compounds to be studied.

Response to Arguments

Applicant's arguments and amendment filed October 11, 2005 have been fully considered but they are not persuasive.

Applicant's argument found on page 4 states that the prior art does not teach the added structural limitations for the positioning device, and specifically that the prior art's teaching of a needle and syringe arrangement does not include "an attachment region," wherein the attachment region is "permanently attachable" to the animal or animal tissue, and further, that the needle and syringe arrangement of the prior art is never immobilized with respect to the sample.

The specification only teaches that the positioning device can be "rendered" attachable to the animal or animal tissue, and never clearly specifies an "attachment region" of the positioning device (see page 12, lines 4-15). Therefore, the needle and syringe arrangement of the prior art meets the limitations of the positioning device, wherein the needle encompasses the attachment region, and the syringe encompasses the casing. The syringe is the casing because it contains the fibre within and when attached to the needle, it has an open end for positioning within an animal or animal tissue (see Figure 2). The needle is the attachment region because, as illustrated in Figure 2, it can be rendered attachable to an animal or animal tissue and allows for attachment to the syringe. Thus, the needle and syringe arrangement meet the limitations for the positioning device.

With regard to the argument that the needle and syringe arrangement is never immobilized with respect to a sample is not relevant because this is merely an intended use of the claimed invention. An intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is

capable of performing the intended use, then it meets the limitations of the claim. As discussed above, the needle and syringe arrangement meet the limitations of the positioning device and therefore, is capable of performing the intended use of attaching to an animal or animal tissue.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jackie DiRamio
Patent Examiner
Art Unit 1641

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
12/20/05